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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,846	05/24/2001	Jacques-Pierre Moreau	00537-182002	5083

7590 01/27/2004

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,846	MOREAU, JACQUES-PIERRE	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Part III DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission (Information Disclosure Statement) filed on 10/31/2003 has been entered.

Status of the claims

Claim 5 is pending

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States...

Claim 5 is rejected under 35 U.S.C. 102(b) as anticipated by Coy et al (US 4,853,371) or Bogden (US 5,411,943). The rejection is maintained for the reasons of record and reiterated as follows:

Coy

Coy teaches a pharmaceutical composition comprising a therapeutically effective amount of the compound of formula β-D-Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr-NH_2 or its pharmaceutically acceptable salt. See claims 1,3. The pharmaceutically acceptable salt can be acetate. See col. 3, line 48.

Bogden

Bogden teaches the use of the same somatostatin analog, β-D-Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr-NH_2, as described in Coy above, for hepatoma treatment. The somatostatin analog can be in a form of acetate salt (col. 4, line 15) and be used in a form of a pharmaceutical formulation comprising a pharmaceutically acceptable carrier (col. 7, lines 15-23).

The referenced pharmaceutical compositions of Coy or Bogden anticipate the instantly claimed pharmaceutical composition comprising an effective amount of acetate salt of β-D-Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr-NH_2 and a pharmaceutically acceptable carrier. In regard to intended use of the composition, it is accepted by courts that arguments related to the intended use of the composition are of little

relevance in determining the patentability of the composition. See, e.g., *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

In regard to previously discussed argument of the applicant that the references do not teach compositions comprising active ingredient in the amounts sufficient to treat delineated diseases or conditions, effective amount for treatment the laundry list of conditions, ranging from sclerosis to cancer to panic attacks, is not identified in the claims. Specification mentions generic dosage range of 250 μg/kg/day to 5.0 mg/kg/day (p. 6) which, again, is not demonstrated to be effective in treatment of any of particular disorders. Teaching of dosages in the cited prior art is fully within the range recited in the instant specification (see Coy, col. 4, lines 34, 35; Bogden col. 7, lines 5,6), and there is no reason to believe that the amounts recited in the references will be completely ineffective in treatment of the disorders mentioned in the instant claims. Since the Office does not have the facilities for examining and comparing applicants' composition with the compositions of the prior art, the burden is on applicant to show differences between the claimed product and the products of the prior art (i.e., that the amount of the active ingredients in the compositions of the prior art is not effective in treatment of the disorders mentioned in the instant claims). See *In re* Best, 562 F.d. 1252, 195 USPQ 430 (CCPA 1977) and *In re* Fitzgerald et al., 205 USPQ 594.

Conclusion.

No claims are allowed

This is an RCE of applicant's earlier Application No. 09/744846. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703)

305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

January 8, 2004

mlb